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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,657	08/14/2001	Jon B. Korshus	0632/1G857-US2	3992

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/12/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/930,657**

Applicant(s)  
**Korshus et al.**

Examiner  
**S. Devi, Ph.D.**

Art Unit  
**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 9, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-43 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

**Election/Restriction**

- 1) Claims 1-43 are pending in the application and are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-23, drawn to a bacterin comprising two non-crossprotective inactivated *B. burgdorferi* isolates, classified in class 424, subclass 93.4
  - II. Claims 24-32, drawn to a method of immunizing an animal by administering the bacterin vaccine, classified in class 424, subclass 9.2
  - III. Claims 33-35, drawn to a bacterin comprising antigenic subunits derived from *B. burgdorferi* isolates, classified in class 424, subclass 234.1
  - IV. Claim 36, drawn to a bacterin comprising two inactivated *B. burgdorferi* isolates and one or more antigenic subunits from *B. burgdorferi*, classified in class 203.1
  - V. Claims 37-41, drawn to a method of use of a bacterin comprising two inactivated isolates, classified in class 424, subclass 93.1
  - VI. Claims 42 and 43, drawn to a method of use of a bacterin comprising at least two non-crossprotective inactivated *B. burgdorferi* isolates and one or more antigenic subunits from *B. burgdorferi*, classified in class 184.1
- 4) Inventions I through VI are distinct from one another. Inventions I, III and IV are drawn to different products, which differ from one another in the number and type of antigens comprised. The product of invention I comprises two non-crossprotective inactivated *B. burgdorferi*, whereas the product of invention III encompasses cross-protective bacterin plus antigenic subunits derived from *B. burgdorferi* isolates. The product of invention IV comprises a

combination of bacterin and antigenic subunits of *B. burgdorferi* isolates. The three products are structurally, antigenically and immunogenically distinct from one another. The product of invention III is not required to practice the methods of inventions II, V and VI.

5) Inventions I and inventions II and V, and inventions IV and VI respectively, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the products of inventions I and IV can be used in a materially different process, for example, as an *in vitro* diagnostic antigenic reagent in a diagnostic assay.

6) Invention IV and invention I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (M.P.E.P § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the bacterin subcombination as claimed for patentability, because the combination product is an individually distinct antigenic composition. And the subcombination bacterin is individually distinct having its own separate utility, for example, as a diagnostic antigen.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

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9) Applicants are asked to note that upon election of claim(s) drawn to a product, the corresponding method claim(s) will be retained as pending claims pursuant to the rejoinder provisions of M.P.E.P 821.04 and will be withdrawn from consideration until such time as the subject matter of elected product claim(s) are deemed allowable. The Examiner in charge of the instant application will then determine if corresponding method claims include all of the limitations of the allowable product claim(s) prior to determining if rejoinder will be permitted under M.P.E.P 821.04.

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 309-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2002

  
S. DEVI, PH.D.  
PRIMARY EXAMINER



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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